



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/020,716 | 02/09/1998 | RUDOLF JUNG | 0815 | 3572 |

27310 7590 07/28/2004

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 09/020,716 | Applicant(s) JUNG ET AL. | |
| | Examiner Elizabeth F. McElwain | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79,90,91,103,105 and 112-116 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79,90,91,103,105 and 112-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 19, 2004 has been entered.

Claims 78, 96, 108 and 117-120 are cancelled.

Claims 103 and 112-116 are newly amended.

Claims 79, 90, 91, 103, 105 and 112-116 are pending and are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections that are not restated below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 79, 90, 91, 103, 105 and 112-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 112-116, and claims 79, 90, 91, 103 and 105 dependent thereon are indefinite and confusing in the recitation of "one or more" with regard to a range of mole percent of

Art Unit: 1638

lysine and a range of mole percent of a sulfur containing amino acid, it is unclear what is intended, since only two ranges appear.

Claims 115 and 116, and all claims dependent thereon, are indefinite in that they are unduly alternative in the multiple recitations of "and/or" in the claims, as stated in the last office action.

Applicants' arguments filed January 19, 2004 have been fully considered but they are not persuasive. Applicants assert that claims 117-120 have been cancelled so that the rejection should be withdrawn. The Examiner maintains the rejection given that claims 115 and 116 are pending and have not been amended.

Claims 79, 90, 91, 103, 105 and 112-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the specification teaches a transformed cereal plant seed having an elevated lysine, methionine and cysteine content (about 10% to about 35% by weight compared to untransformed cereal plant seed) comprising the modified hordothionin gene of SEQ ID NO: 2 (HT12), vectors, plant cells and transformed plants comprising said modified hordothionin gene.

The specification does not teach the range of 7 mole% to 40 mole % of lysine or 6 mole% to 40 mole % of sulfur-containing amino acids for any seed protein and further does not

Art Unit: 1638

teach any seed proteins having both of these ranges. Therefore, in view of the reasons of record set forth in the scope of enablement rejection set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001; and given the lack of working examples of protein coding sequences having the claimed ranges of mole % lysine and sulfur containing amino acids; the absence of guidance with regard to identifying such sequences and transforming them into plants; and given the breadth of the claims which encompass seed proteins that have virtually unlimited modifications to produce proteins having the claimed ranges of mole % lysine and sulfur containing amino acids; it would require undue experimentation by one of ordinary skill in the art to make and/or use the claimed invention, as stated in the last office action.

Applicants' arguments filed January 19, 2004 have been fully considered but they are not persuasive. Applicants assert that the rejection should be withdrawn given that the specification demonstrates increased lysine obtained by using one construct of HT12 and an endosperm specific promoter, and the Declaration of Jung provides results on using a construct comprising ESA and an endosperm specific promoter. The Examiner maintains that the rejection is proper given that applicants one working example is not sufficient to enable the broad claims. As stated in the last office action, the example provided in the Declaration of Jung does not provide information to support the claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 103 is rejected under 35 U.S.C. 102(b) as being anticipated by Powell et al (US Patent 3,909,288).

The claim is drawn to a food or feed product derived produced from the transformed plant seed of claim 114.

Powell et al teach oil and starch produced from corn, wherein the oil and starch would be the same as that claimed, given that the transgene introduced into the plant seed would not confer any patentably distinguishable properties from any corn oil or corn starch, including that taught by Powell et al.

Claims 79, 90, 91, 103, 105 and 112-116 remain rejected under 35 U.S.C. 103(a) as being obvious over Rao et al (U.S. Patent 5,885,802) in view of Applicants' Admission. This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Applicants' arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicants assert that no motivation has been provided to use an endosperm preferred promoter in combination with the teachings of Rao. The Examiner maintains that it

Art Unit: 1638

would have been obvious to substitute an endosperm preferred promoter in the method of Rao given that Rao's invention is drawn to producing elevated levels of lysine in seeds.

Claims 79, 90, 91, 103, 105 and 112-116 remain rejected under 35 U.S.C. 103(a) as being obvious over Rao et al (U.S. Patent 5,990,389) in view of Applicants' Admission. This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Applicants' arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicants assert that no motivation has been provided to use an endosperm preferred promoter in combination with the teachings of Rao. The Examiner maintains that it would have been obvious to substitute an endosperm preferred promoter in the method of Rao given that Rao's invention is drawn to producing elevated levels of lysine in seeds.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM